PDUFA V Clinical Outcomes Assessment Development and Implementation: Opportunities and Challenges Public Workshop April 1, 2015 – FDA, White Oak Campus

Time	Session	Speakers	Additional Panelists
7:30-8:30am	**Registration and Sign-In**		
8:30-8:45am	**Welcoming Remarks**	Janet Woodcock, Director, Center for Drug Evaluation and Research	
8:45-9:15am	**Introduction** PDUFA V context and goals of the meeting Overview of background package, expectations of meeting	**Co-Chairs:** Theresa Mullin, Director, Office of Strategic Programs Elektra Papadopoulos, Acting Associate Director, Study Endpoints Team	
9:15-10:15am	**Session 1: Experiences with FDA Guidance on Patient-Reported Outcome Measures and the Clinical Outcome Assessment Tool Qualification Process** Barriers and challenges Development of the proposed Clinical Outcomes Initiative Speaker presentations	**Moderator:** Elektra Papadopoulos, FDA Katarina Halling, AstraZeneca Bryce Reeve, University of North Carolina Paul Kluetz, FDA Elektra Papadopoulos, FDA	
10:15-10:25am	**Break**		
10:25-10:55am	**Session 1: Experiences with FDA Guidance on Patient-Reported Outcome Measures and the Clinical Outcome Assessment Tool Qualification Process, cont.** Panel discussion and questions	**Moderator:** Elektra Papadopoulos, FDA Katarina Halling, AstraZeneca Bryce Reeve, University of North Carolina Paul Kluetz, FDA	Wen-Hung Chen, FDA Gabriela Lavezzari, PhRMA Bob Dworkin, University of Rochester Medical Center

Time	Session	Speakers	Additional Panelist
10:55-12:10pm	**Session 2: Advancing Measurement Strategies for Clinical Outcome Assessment Tools** Use of previously labeled clinical outcome assessment tools as an adjunct to regulatory qualification Speaker presentations Panel discussion and questions	**Moderator:** Ashley Slagle, FDA Ann Marie Trentacosti, FDA Jean Paty, Quintiles Stephen Joel Coons, PRO Consortium	Ellis Unger, FDA Alicyn Campbell, Genentech Dennis Turk, University of Washington Tom Sellers, Takeda Bray Patrick-Lake, Clinical Trials Transformation Initiative
12:10-1:10pm	**Lunch**		
1:10-1:40pm	**Session 2: Advancing Measurement Strategies for Clinical Outcome Assessment Tools** Continue panel discussion and questions	**Moderator:** Ashley Slagle, FDA Ann Marie Trentacosti, FDA Jean Paty, Quintiles Stephen Joel Coons, PRO Consortium	Ellis Unger, FDA Alicyn Campbell, Genentech Dennis Turk, University of Washington Tom Sellers, Takeda Bray Patrick-Lake, Clinical Trials Transformation Initiative
1:40-2:40pm	**Session 3: Use of Clinical Outcome Assessment Tools in Multinational Trials** Stakeholder Perspectives	**Moderator**: Ashley Slagle, FDA Maria Isaac, EMA Andrew Mulberg, FDA Donald Patrick, University of Washington Debra Silberg, Shire Laura Lee Johnson, FDA	
2:40-2:50pm	**Break**		

Time	Session	Speakers	Additional Panelist
2:50-4:20pm	**Session 4: Strategies Going Forward** Key learnings from the PDUFA: Where Do We Go From Here? Regulatory Perspective PROMIS (Patient Reported Outcomes Measurement Information System) Patient Perspectives Industry Perspective Researcher/Academia Perspective Panel discussion and questions	**Moderator:** Theresa Mullin, FDA Paul Kluetz, FDA Janet Maynard, FDA Jim Witter, NIH Jeff Allen, Friends of Cancer Research Kim McCleary, Faster Cures Marc Boutin, National Health Council Jennie Spotila, Patient, CFS/ME Working Group Roslyn Schneider, Pfizer C. Daniel Mullins, University of Maryland	
4:20-4:50pm	**Open Public Comment**	**Moderator:** Pujita Vaidya, FDA	
4:50-5:00pm	**Closing Remarks**	Elektra Papadopoulos, FDA	